UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,962	10/02/2006	Dimiter S. Dimitrov	251149	9167

45733 7590 09/17/2009

LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com
Chgpatent1@leydig.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,962	DIMITROV ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *1-30,41,43-45,56,58-60,71 and 73-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-40,42,46-55,57,61-70,72 and 76-84* is/are rejected.

7)☒ Claim(s) *41,56 and 71* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 5/4/2009 is acknowledged. The traversal is on the ground(s) that Group I and Group II are drawn to the same special technical feature and that a search with respect to Group I or II would uncover prior art for both groups. This is not found persuasive because the grouped inventions do not necessarily have the same special technical feature. Note the Moulard reference is drawn to a fusion molecule having the same function as claimed which inhibits HIV, such as binding CCR5, which is a specificity of one of the fusion molecules within the scope of those instantly claimed, see claim 8. Thus, such fusion molecules are known. Also, of note, the method of Group II is broadly drawn to inhibiting any viral infection, which may be performed with various drugs, etc. Further, the fusion molecule, as claimed, in Group II may be used for different methods, such as, ELISA assays, etc., see the Moulard reference. Thus, unity of invention does not exist and the groups are drawn to different special technical features. Applicant's argument that a search for the claimed subject matter would likely uncover art for both groups is also not found persuasive, because as seen by Moulard and recognized by the state of the prior art, such fusion molecules containing antibody fragments may be used in various methods, such as, in vitro assays, as well as in vivo. Thus, a search for one group would not necessarily uncover art for the other. Applicant's request for consideration of rejoinder is acknowledged and will be considered at the time of allowance of the product claims.

The election of species of SEQ. ID NO. 2 (m9 scFv) is also acknowledged. Claims 1-30 have been withdrawn as not reading on the elected invention. Claims 43-45, 58-60 and 73-75 are also withdrawn for not reading on the elected species of SEQ ID. NO. 2.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The use of the trademark INVITROGEN (p. 11) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-40, 42, 46-55, 57, 61-70, 72 and 76-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Bitton et al. (hereinafter Bitton, Eur. J.

Immunol., 1998), as evidenced by Saphire (Actqa Cyrstalogr D Biol Crystallogr. 2001).

Bitton discloses a fusion molecule comprising an scFv fragment and an Fc region of an antibody, via a linker (such linker would be expected to be at least somewhat flexible under some circumstance). Specifically, the authors state in the abstract that "The ScFv were linked to the signal-transducing γ chain of the FcγRIII, with or without spacer region". The ScFv-b12 derives from the b12 antibody which is an IgG antibody and binds a conserved binding site of gp120, as evidenced by Saphire (see Abstract). The fusion molecule binds a conserved HIV epitope from the envelope glycoprotein (the CD4 binding domain and part of the V2 loop of gp120), see abstract and page 4178. These are the same epitopes as set forth in the instant claims, including claims 32, 34 and 35. The disclosed fusion molecule would be inherently expected to satisfy the functional characteristics claimed, including binding to an epitope that is inaccessible to whole immuoglobulin molecules, enhancement of the fusion protein binding by the HIV co-receptors (see abstract and instant claims 31 and 36-38), since is has the same components as instantly claimed and binds the same HIV targets. Further, the same compositions must have the same properties. The fusion molecule cDNA was transfected into HeLa host cells, see page 4180. The fusion molecule was used in binding assays which would contain a pharmaceutically acceptable excipient, including water, which would also read on an additional "active" agent (as water is active for hydration), meeting the limitations of claims 76, 77, 79, 80, 82 and 83. The gp120

envelope protein in its isolated form is within the scope of inactivated virus in claims 78, 81 and 84.

Claims 31-40, 42, 46-55, 57, 61-70, 72 and 76-84 are rejected under 35 U.S.C. 102(a) as being anticipated by Dimitrov (WO 03/033666).

Dimitrov discloses a fusion molecule (antibody fragments) comprising an scFv fragment and an Fc region of an antibody via a linker (see page 34, abstract and claims 1 and 15+). The fusion molecule derives from an IgG antibody and binds a conserved binding site of gp120, as evidenced by Saphire. The fusion molecule binds a conserved HIV epitope from the envelope glycoprotein (the CD4 binding site), see claims. These are the same epitopes as set forth in the instant claims, including claims 32, 34 and 35. The disclosed fusion molecule would be inherently expected to satisfy the functional characteristics claimed, including binding to an epitope that is inaccessible to whole immuoglobulin molecules (instant claim 31) and the enhancement of fusion protein binding by HIV co-receptors CXCR4 and CCR5 (instant claim 9 and abstract) given Dimitrov teaches the same components as instantly claimed and binds the same HIV targets. Further noted, the same compositions must have the same properties. The WO patent also discloses host cells, see claim 33 and pharmaceutical compositions of the fusion molecule and host cells and such compositions with other active agents (see pages 10, 18 and claim 36). The isolated gp120 envelope protein and viral vectors, etc. are within the scope of inactivated virus as set forth in claims 78, 81 and 84, see pages 20-22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-40, 42, 46-55, 57, 61-70, 72 and 76-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bitton et al. (hereinafter Bitton, Eur. J. Immunol., 1998, as evidenced by Saphire Actqa Cyrstalogr D Biol Crystallogr. 2001) or Dimitrov (WO 03/033666) in view of De Clercq (Verh K Acad Geneeskd Belg. 1998).

Bitton and Dimitrov disclose a fusion molecule comprising an scFv fragment and an Fc region of an antibody, as set forth above.

While Bitton and Dimitrov teach compositions which may be construed as further comprising other active agents for the reasons set forth in the rejection under 35 USC

102 (above), they fail to specifically teach the use of some of the specific additional active agents as set forth in claims 78, 81 and 84. However, both Bitton and Dimitrov teach compositions that are useful inhibiting HIV and Dimitrov teaches that the methods may be used for HIV patients already being treated with additional drugs, see page 18.

The use of combination therapy for inhibiting HIV is very well known in the art with combination therapies including drugs such as AZT, etc., as taught by De Clercq (see abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the fusion molecule composition disclosed by both Bitton and/or Dimitrov for inhibiting HIV with AZT because AZT is a well-known HIV drug which may be used in combination therapy as taught by De Clercq which provides the clear advantage of improved treatment. Also note that combining two active agents for the same purpose is *prima facie* obvious. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claim Objections/Allowable Subject Matter

Claims 41, 56 and 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, as noted above,

these claims have only been examined to the extent they read on SEQ ID NO: 2 in accordance with Markush/Election of Species practice as discussed hereinabove.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./

Examiner, Art Unit 1648

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646